

- C/ 4. (Amended) The liquid preparation of Claim 1, which contains a surface active agent selected from the group consisting of a non-ionic surface active agent, a cationic surface active agent and an ampholytic surface active agent.

Remarks

Reconsideration and allowance of claims 1 through 4, all of the claims pending in the application, are respectfully requested in view of the above amendments and the following remarks. No claims have been added or cancelled.

Claims 2 and 4 have been rejected under 35 USC §112, second paragraph, for lack of antecedent basis. However, it is believed that claim 2 is proper, since claim 1 is an open claim and claim 2 recites an additional component included in the liquid preparation of claim 1. It is also believed that the rejection of claim 4 has been overcome by the above-proposed amendment of claim 4.

It will be recalled that the invention relates to compositions which are safe for cleaning, disinfecting, rinsing and storing contact lenses. Due to the use of low levels of a novel amine compound, the compositions are highly effective, yet extremely safe.

Claims 1 and 3 have been rejected under 35 U.S.C. §102(b) as defining an invention that is anticipated by the Patent Abstract of Japan (JP-A-10-319358 to Menicon Co. Ltd.). This rejection is respectfully traversed.

The Examiner states that the Patent Abstract of Japan teaches the use of alkyl amine (correctly allylamine) of repeating units at the claimed concentrations as preserving agents. However, the concentration of the polyallylamine in preserving solution disclosed in JP-A-10-319358 is from 0.01 to 10 w/v%, namely 100 to 100,000 ppm. Accordingly, the presently claimed liquid preparation is not anticipated by JP-A-10-319358.

We note further that the Patent Abstract of Japan 10-319358 was cited in the PCT International Search Report as of Background interest only. Moreover, the PCT/1B/338 Preliminary Examination Report indicated that the claims were novel when compared to all of the cited prior art. The report further found inventive step met. For the examiner's information, we enclose herewith a copy of Patent Abstract of Japan 10-319358 and the automatic machine translation of JP-A-10-319358. The Patent Abstract of Japan discloses that the distributing and preserving solution contains not less than 0.01 w/v%, preferably not less than 0.1 w/v%, of at least one member selected from the group consisting of a polyallylamine having repeating units of formula I, a salt of the polyallylamine, and a polymer having repeating units of formula II. Claim 2 of JP-A-10-319358 recites that concentration of these compounds is from 0.01 to 10 w/v%. Thus, the levels of use are very different in the reference as compared to what applicants claim.

Claims 1 and 3 have not been rejected under 35 USC §103 as being unpatentable over the Patent Abstracts of Japan 10-319358 and the Patent Abstracts of Japan 10-108899. However, applicants present the following argument as part of a complete response to the Office Action.

In light of the above, claims 1 and 3 are also patentable over the cited references. Again, both references were previously cited in the International stage and found to not adversely affect the patentability of the claims.

The present invention is directed to a multi-purpose liquid preparation for contact lenses which has all functions for cleaning, rinsing, disinfecting and preserving contact lenses, and which can exhibit an excellent antibacterial or antiseptic effect while securing a high safety to the eyes.

Multi-purpose liquid preparations for contact lenses are required to have a high safety to the eyes while exhibiting a high antibacterial activity. However, known liquid preparations for contact lenses are unsatisfactory in antibacterial activity or safety to the eyes.

Applicants' claimed liquid preparation contains 0.3 to 50 ppm of a specific polyamine as an antibacterial agent. It exhibits a high antibacterial activity in spite of a very low concentration of the antibacterial agent. According to the present invention, the concentration of an antibacterial agent can be greatly decreased to raise the safety to the eyes while maintaining a required high antibacterial activity.

Such a result is demonstrated by the data in the specification.

JP-A-10-319358 is directed to a distributing solution (shipping solution) used for preserving contact lenses in the distribution process until patients purchase the lenses after the manufacturing (see paragraph [0003]).

The '358 reference discloses that the solution contains a polyallylamine having allylamine recurring units. However, as apparent from the reference itself, the '358 reference teaches that the polyallylamine is used as a component for suppressing a change of the base curve of a contact lens at the time of the distribution (see [0005] "Problem(s) to be Solved by the Invention"). The '358 reference also teaches that the concentration of the polyallylamine in the solution is not less than 0.01 w/v% (*i.e.*, not less than 100 ppm) and preferably not less than 0.1 w/v% (*i.e.*, not less than 100,000 ppm). The purpose for and amount of the polyallylamine are materially different, and there is no reason for or motivation to change the level of usage to achieve applicants' results.

JP-A-10-319358 discloses at paragraphs [0024] and [0031] as follows (in words selected to better provide accurate meaning to the machine translation):

"[0024] In the preserving liquid for distribution of contact lenses of the present invention, compound (A) used as an effective component for reducing change of the base curve of a contact lens at the time of distributing contact lenses in a wet-preserved state is at least one of the polyallylamine, its salt and polymer (A-I). These may be used alone or in admixture thereof."

"[0031] For sufficiently exhibiting the effect of reducing the change of the base curve of a contact lens at the time of distributing contact lenses in a wet-preserved state, it is desirable that the content of the compound (A) in the preserving liquid for distribution of contact lenses is not less than 0.01 w/v%, preferably not less than 0.1 w/v%. Also, in order to avoid a possibility of occurrence of handling problems such that contact lenses become easy to be contaminated at the time of drying due to excessive rise in viscosity of the preserving liquid for distribution, it is desirable that the content is not more than 10 w/v%, preferably not more than 3 w/v%."

Moreover, JP-A-10-319358 does not teach or suggest that polyallylamine has an antibacterial activity. Therefore, the teachings of JP-A-10-319358 do not lead a person skilled in the art to use the polyallylamine in a concentration of 0.3 to 50 ppm, as claimed, or even higher levels for this purpose. Even if a person skilled in the art is led to incorporate the polyallylamine in a contact lens solution, it is not expected from the cited reference that the polyallylamine exhibits a high antibacterial activity even at very low concentrations, thus providing a contact lens solution having both a high antibacterial activity and a high safety to the eyes.

In light of the above, it is believed that the liquid preparation as claimed in claims 1 and 3 of the present application are unobvious over JP-A-10-319358.

Claims 2 and 4 have been rejected under 35 USC §103 as being unpatentable over the Patent Abstracts of Japan 10-319358 and the Patent Abstracts of Japan 10-108899. In light of the above, these claims are also patentable over the cited references.

In addition to the above, applicants point to the Examples and Comparative Examples summarized in the Description at pages 18 through 20, in particular Table 1. Given these

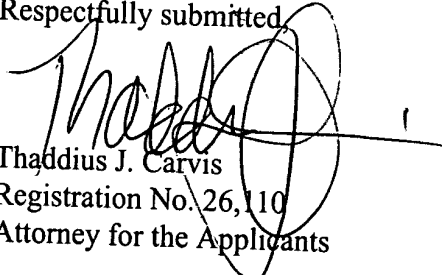
results and the lack of any suggestion by the prior art to do what applicants' now show for what they claim, the rejection for obviousness is clearly rebutted.

Rebuttal evidence of the type presented in the original Description is proper in that it consists of a showing that the claimed compound possesses unexpected properties. *In re Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901. It is noted that any explicit findings on the similarities and differences between the closest disclosed prior art of record and the invention should take into account the invention as a whole, which includes the new properties or their improvement. In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983), the Court noted that "the question under 35 U.S.C. §103 is not whether the differences [between the claimed invention and the prior art] would have been obvious" but "whether the claimed invention as a whole would have been obvious." (emphasis in original). A showing of unexpected results based on evidence, as presented by applicant in the Description as filed is believed sufficient to rebut a *prima facie* case of obviousness, should one have been established by the references themselves.

Applicants have made a significant advance in the art and have described it in terms definitely and clearly distinguishable from the prior art. Accordingly, reconsideration and allowance of all pending claims are believed in order and such actions are earnestly solicited.

May 13, 2003

Respectfully submitted,


Thaddius J. Carvis
Registration No. 26,110
Attorney for the Applicants

WARE, FRESSOLA, VAN DER
SLUYS & ADOLPHSON LLP
Bradford Green, Bldg. Five
755 Main St., P.O. Box 224
Monroe, CT 06468
Telephone: (203) 261-1234
Facsimile: (203) 261-5676



Serial No. 10/088,770

Claims Showing Changes

4. (Amended) The liquid preparation of Claim 1, [wherein the] which contains a surface active agent [is a member] selected from the group consisting of a non-ionic surface active agent, a cationic surface active agent and an ampholytic surface active agent.